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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Viren A. Thakur
Group Art Unit : 1794
Applicant : Lee Michael Teras et al
Application No. : 10/603,279
Confirmation No. : 4437
P&G Docket No. : 9286
Filed : June 25, 2003
For : METHODS FOR REDUCING ACRYLAMIDE IN CORN-BASED FOODS HAVING REDUCED LEVELS OF ACRYLAMIDE, AND ARTICLE OF COMMERCE

DECLARATION OF DAVID VINCENT ZYZAK SUBMITTED
PURSUANT TO 37 C.F.R. § 1.131

Sir:

I, David Vincent Zyzak, declare that:

1. I am a Senior Scientist at The Procter & Gamble Company ("P&G"), Winton Hill Business Center, 6300 Center Hill Avenue, Cincinnati, Ohio, 45224.

2. I understand that myself, Lee Michael Teras, Stephen Paul Zimmerman, Robert Alan Sanders, Marko Stojanovic, Peter Yau Tak Lin, Maria Dolores Martinez-Serna Villagran, John Keeney Howie, and Richard Gerard Schafermeyer ("Zyzak") are the named inventors of U.S. patent application Serial No. 10/603,279 (the "Zyzak '279 application"). I make this declaration in support of Zyzak's claim that the invention claimed in the Zyzak '279 application was made before the September 19, 2002 priority date of Elder et al.'s U.S. patent application 10/247,504, which published as US 2004/0058054 ("Elder").

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3. I received a B.S. in Chemistry from Old Dominion University in 1989. I received a Ph.D. in Biochemistry from the University of South Carolina in 1995. My Ph.D. thesis was "Studies on the Maillard reaction: mechanism of the fructosamine assay, decomposition of Amadori adducts on protein, and reaction of 3-deoxyglucosone with arginine residues in protein."

4. Since I earned my Ph.D. in 1995, I have continuously been employed in research and development positions in the food industry. I am the author of numerous publications related to my research and development work in the food industry.

5. From August 1995 until November 1997, I worked for Nestle in New Milford, Connecticut, as a Developmental Technologist and Process Flavor Chemist.

6. From November 1997 until September 1999, I worked for Takasago Institute, a flavors and fragrances company located in Rockleigh, New Jersey. My position at Takasago was Senior Scientist.

7. In September 1999, I started working for P&G in Cincinnati, Ohio. When I joined P&G, my position was Scientist in P&G's Food and Beverage Analytical/Microbiology Division. In September 2000, I was promoted to Senior Scientist. In 2002, the name of the Food and Beverage Analytical/Microbiology Division was changed to Snacks and Beverage Analytical/Microbiology. In 2004, the name was changed again to Household Care Analytical. Today I am a Senior Scientist in P&G's Household Care Analytical Division. I am also the Coordinator of Coffee Analytical Support. During my employment at P&G, I have worked continuously in research and development related to snack food products.

8. I conducted an experiment entitled "Use of Asparaginase to decrease acrylamide formation in cooked foods" (the "Experiment"). The Experiment was conducted at the Winton Hill Business Center, a P&G facility in Cincinnati, Ohio.

9. I recorded the details of how I conducted the Experiment on pages 2 and 3 in my P&G Lab Notebook #WHS 2688.

10. A true and correct copy of the cover, instruction sheet, and pages 2 and 3 of my P&G Lab Notebook #WHS 2688 were previously filed in this case and were attached to a declaration in case no 9043MXL, which is US Patent Application No. 10/606,137. Those copies are hereby incorporated by reference herein in their entirety.

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The dates on Exhibit A have been blacked out, but all of the dates are before September 10, 2002.

11. In the Experiment's first step, baking potatoes were boiled for two hours. The potatoes were then peeled and mashed with a fork.

12. Next, 100 grams of the mashed potatoes that were prepared in the Experiment's first step were mixed with 100 grams of distilled and de-ionized water, and the resulting mixture was homogenized until it was uniform and no lumps were visible.

13. Next, four samples were prepared. Each sample consisted of 30 grams of the mixture described above in paragraph 12, mixed with 30 grams of distilled and de-ionized water. Each sample was placed in an eight ounce glass jar, and the four samples were labeled A1, A2, E1 and E2, respectively.

14. A solution was prepared consisting of 500 units of asparaginase dissolved in 1.0 milliliter of distilled and de-ionized water. One unit of asparaginase is defined as the amount of asparaginase that will liberate 1.0 micromole of NH₃ from L-asparagine per minute at 37° C and a pH of 8.6. The asparaginase I used was ordered before September 10, 2002, from VWR, a vendor that arranges ordering and shipping of scientific products within P&G. A true and correct copy of the email I sent to VWR asking that they order the asparaginase from Sigma-Aldrich Inc. was included as Exhibit B in case no. 9043MXL, which is US Patent Application No. 10/606,137. That copy is hereby incorporated by reference herein in its entirety. Furthermore, a true and correct copy of the Sigma-Aldrich Inc. invoice for the asparaginase order was previously filed in this case and was attached as Exhibit C in case no. 9043MXL, which is US Patent Application No. 10/606,137. That copy is hereby incorporated by reference herein in its entirety. The dates on Exhibits B and C have been blacked out, but all of the dates are before September 10, 2002.

15. 100 microliters of the asparaginase solution described above in paragraph 14 was added to the jar labeled E1, and 100 microliters of the same solution was added to the jar labeled E2. No asparaginase solution was added to the jars labeled A1 and A2, as those jars served as controls.

16. Next, the four samples described above in paragraph 15 were allowed to stand at room temperature for 30 minutes with occasional stirring to allow the asparaginase in the jars labeled E1 and E2 to react with the asparagine in the potatoes.

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17. The four samples described above in paragraph 16 were then micro-waved for two minutes to deactivate the asparaginase in the jars labeled E1 and E2.

18. The four samples described above in paragraph 17 were then micro-waved in two minute sessions until the samples were cooked. This required four two minute sessions, for a total of eight minutes.

19. The four samples described above in paragraph 18 were then sent to P&G's Foods and Beverages Analytical/Microbiology lab for analyses of the acrylamide, asparagine and aspartic acid contents of the samples. Deborah K. Ewald performed the acrylamide testing, and Janice N. Batchelor performed the asparagine and aspartic acid testing.

20. I received the results of the acrylamide analysis from Deborah Ewald. These results were tabulated in a spreadsheet, a true and correct copy of which was previously filed in this case and was submitted as Exhibit D in a declaration in case no. 9043MXL, which is US Patent Application No. 10/606,137. That copy is hereby incorporated by reference herein in its entirety. I also recorded these results on page 3 of my Lab Notebook #WHS 2688 (Exhibit A). The dates on Exhibit D have been blacked out, but all of the dates are before September 10, 2002.

21. The lab results show that for the jars labeled A1 and A2 (the two samples that were not treated with the asparaginase solution), the acrylamide levels were 21,605 and 20,543 parts per billion ("ppb") respectively. For the jars labeled E1 and E2 (the two samples that were treated with the asparaginase solution), the acrylamide levels were 385 and 164 ppb, respectively.

22. The results described above in paragraphs 20 and 21 demonstrate that, in the case of the samples in the jars labeled E1 and E2, the addition of asparaginase to the mashed potato mixture caused the acrylamide levels to be reduced by over 98% after cooking, as compared to the levels of acrylamide in the untreated samples in the jars labeled A1 and A2.

23. I received the results of the asparagine and aspartic acid analyses from Janice N. Batchelor. Those analyses were performed before September 10, 2002. A true and correct copy of those results was previously filed in this case and was attached as Exhibit E in case no. 9043MXL, which is US Patent Application No. 10/606,137. That

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copy is hereby incorporated by reference herein in its entirety. I also recorded those results on page 3 of Lab Notebook #WHS 2688 (Exhibit A).

24. The lab results I received show that for the jars labeled A1 and A2 (the two samples that were not treated with the asparaginase solution), the asparagine levels were 1131.0 and 1041.6 parts per million ("ppm"), respectively. For the jars labeled E1 and E2 (the two samples that were treated with asparaginase solution), the asparagine levels were 129.5 and 195.5 ppm, respectively. For the jars labeled A1 and A2 (the two samples that were not treated with the asparaginase solution), the aspartic acid levels were 189.2 and 178 ppm, respectively. For the jars labeled E1 and E2 (the two samples that were treated with the asparaginase solution), the aspartic acid levels were 1307 and 1826.5 ppm, respectively.

25. The results described above in paragraphs 23 and 24 demonstrate that, in the case of the samples in the jars labeled E1 and E2, the addition of asparaginase to the mashed potato mixture caused the asparagine levels to be reduced by over 85% after cooking, as compared to the levels of asparagine in the untreated samples in the jars labeled A1 and A2.

26. The results described above in paragraphs 23 and 24 demonstrate that, in the case of the samples in the jars labeled E1 and E2, the addition of asparaginase to the mashed potato mixture caused the aspartic acid levels to be increased by over 753% after cooking, as compared to the levels of aspartic acid in the untreated samples in the jars labeled A1 and A2.

27. I explained the Experiment, its results, and the significance of the results, to Dr. Kwan Y. Lee, a Principal Scientist in P&G's Food and Beverages Analytical/Microbiology Division in Cincinnati, Ohio. I also showed him pages 2 and 3 of my P&G Lab Notebook #WHS 2688 (Exhibit A). Dr. Lee signed and dated page 2 of my entry in Lab Notebook #WHS 2688. He also dated page 3, but did not sign it. I believe that Dr. Lee's failure to sign page 3 was an oversight. The dates on Exhibit A have been blacked out, but all of the dates are before September 10, 2002.

28. I understand that claim 1 of the Zyzak '279 application reads as follows:

A method for removing asparagine or converting asparagine to a different substance by hydrolyzing the amide group of the asparagine to form aspartic acid in a

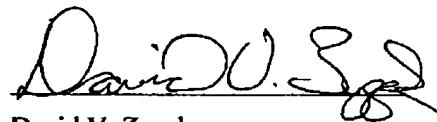
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corn-based food material comprising adding asparaginase enzyme to the food material before heating.

29. The Experiment discussed above in paragraphs 11 through 19 corresponds to claim 1 of the Zyzak '279 application. The Experiment, while implementing mashed potatoes, can be directly applied to a corn-based food material as described in this patent application.

30. Immediately after completing the experiments discussed in paragraphs 11 through 19, and receiving the results discussed in paragraphs 20 through 24, I worked diligently with my co-inventors and a patent attorney employed by the Procter & Gamble Company to further reduce the present invention to practice and to prepare and file U.S. patent application Serial No. 10/603,279.

31. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the Zyzak '279 application or any patent issuing therefrom.



David V. Zyzak

May 8, 2008

Dated

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Filed 14 April 2008

Paper 27

8 UNITED STATES PATENT AND TRADEMARK OFFICE
9 BEFORE THE BOARD OF PATENT APPEALS
10 AND INTERFERENCES

13 DAVID VINCENT ZYZAK,
14 ROBERT ALAN SANDERS, MARKO STOJANOVIC,
15 DAVID CAMMIADE, PETER YAU TAK LIN,
16 MARIA DOLORES MARTINIZE-SERNA VILLAGRAN,
17 JOHN KEENEY HOWIE, and
18 RICHARD GERARD SCHAFERMEYER

20 Junior Party
21 (Application 10/606,137),
22
23 v.
24

25 VINCENT ALLEN ELDER,
26 JOHN GREGORY FULCHER, and
27 HENRY KIN-HANG LEUNG

29 Senior Party
30 (Patent 7,037,540).
31

33 Patent Interference No. 105,579
34 (Technology Center 1700)
35

37 Before Schafer; Lane, and Moore, Administrative Patent Judges.
38

39 Lane, Administrative Patent Judge.

41 Judgment– Arbitration – Bd.R. 126(f)

42 The parties have filed an arbitrator's decision. (Paper 25).¹ In that
43 decision, the arbitrator concluded that junior party Zyzak "was both first to
44 conceive and first to reduce to practice the subject matter of the count [i.e., count
45 1]" and that "priority of invention lies with" Zyzak. (Paper 25 at 9).

1 The parties were authorized to undertake arbitration under Bd. R. 126 (Paper 23) and the parties filed an agreement to arbitrate. (Paper 24).

1 The parties agree that judgment should be entered against senior party
2 Elder. (Paper 26 at 2).

3 It is

4 ORDERED that judgment on priority as to Count 1 (Paper 1 at 4),

5 the sole count of the interference, is entered against senior party Elder;

6 FURTHER ORDERED that claims 1-13 of Elder patent 7,037,540
7 be CANCELLED, 35 U.S.C. § 135(a);

8 FURTHER ORDERED that the parties are directed to 35 U.S.C.
9 § 135(c) and Bd. R. 205 regarding the filing of settlement agreements; and

10 FURTHER ORDERED that a copy of this judgment and the
11 arbitration award shall be entered into the administrative record of Elder patent
12 7,037,540 and Zyzak application 10/606,137.

13

14 /Richard E. Schafer/)
15 RICHARD E. SCHAFER)
16 Administrative Patent Judge)
17)
18)
19 /Sally Gardner Lane/)
20 SALLY GARDNER LANE) BOARD OF PATENT
21 Administrative Patent Judge) APPEALS AND
22) INTERFERENCES
23)
24 /James T. Moore/)
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